

COLORADO STATE BOARD OF PHARMACY
October 22, 2009

Minutes

The Colorado State Board of Pharmacy meeting was convened by President Paul Limberis, R.Ph., at approximately 8:32 a.m. on Thursday, October 22, 2009 at 1560 Broadway, Conference Room 1380, Denver, CO 80202. Notice of this meeting was given in accordance with Division of Registrations Policy Number 80-17.

Board members attending were: Mary K. Arceneaux, R.Ph., Jeannine G. Dickerhofe, R.Ph., Rich Doyle, R.Ph., E. Katherine Edelblut, R.Ph., Leonard Hierath, P.E., Paul Limberis, R.Ph., and Averil Strand, R.N.

Staff members attending were Wendy Anderson, R.Ph., Program Director; Chris Gassen, R.Ph., Chief Inspector; Susan Martin, R.Ph., Inspector; and Tia Johnson, Complaint/Licensing Specialist. Also present was Jo Kaye, Assistant Attorney General to advise the Board.

APPROVAL OF MINUTES

The Board approved the minutes from the September 17, 2009 meeting.

ADDITIONS TO THE AGENDA

None

APPEARANCES

None

HEARINGS

The Board conducted a public hearing concerning additions to or amendments to regulations 5.00.00, 6.00.00, 14.00.00, 15.00.00, 16.00.00, and 19.00.00 (3 CCR, 719-1). The hearing began at 9:30 a.m. and was held in Conference room 1380 at 1560 Broadway, Denver, Colorado 80202. The Board discussed the proposed changes to the rules then adopted the rules as amended.

REPORTS

President's Remarks

Mr. Limberis told the Board about a drug take back program that will begin soon at Denver Health Medical Center.

Program Director's Report

Ms. Anderson reminded the Board that they would be choosing members for the Patient Safety Taskforce in November 2009. She also told the members that the Board would be electing new officers in November as well. She provided updates on the Electronic Prescription Drug Monitoring Program and reminded the members that pharmacist and pharmacy intern renewal ends October 31, 2009.

The Board discussed a proposed change to Rule 4.01.00 and voted to move the proposed change to hearing. The Board reviewed proposed changes to rule 5.01.31(e)(8) and directed staff to do further revisions and bring the proposed changes back at a future meeting. The Board then noted its meeting dates for 2010, 2011, and 2012.

Colorado Pharmacists Society (CPS) – Rich Doyle, RPh

The CPS Annual Fall Meeting was held September 24-26, 2009 at the Radisson Denver Stapleton Plaza Hotel. Twelve hours of ACPE approved continuing education was provided. The Friday program was developed by members of the CPS Academy of Health System Pharmacists and seven hours of education of interest to hospital, managed care and long term care pharmacists was provided. The Saturday program was more general in scope and included a new drug update and programs focused on the management of the disease states of diabetes, hypertension and hyperlipidemia.

The recipients of the 2009 Bowl of Hygeia award and the Distinguished Young Pharmacist of the Year award were announced at the CPS 2009 Annual Fall Meeting. They are as follows:

- 2009 Bowl of Hygeia Award – Dennis Helling
- 2009 Distinguished Young Pharmacist of the Year Award – Nancy Gallegos

CPS is promoting the Annual Patient Safety Conference, “Promoting Patient Safety in Tough Times” which will be held November 13, 2009 at the Children’s Hospital. The Keynote Speaker will be Michael Leonard, MD, from Kaiser Permanente. For more information, contact Kristin at 720-330-6036 or e-mail admin@coloradopatientsafety.org.

CPS is promoting the Colorado Dept of Public Health and Environment Immunization Program’s conference "Epidemiology and Prevention of Vaccine Preventable Disease" on November 16 and 17, 2009 at the Westin Westminster. This two day CDC program will provide the latest information for providers regarding immunizations and is approved for 14 hours of ACPE credits. For more details, please contact Lynn McCracken, Colorado Department of Public Health and Environment Immunization Program, 303-692-2447, 1-800-886-7689 ext. 2447 or lynn.mccracken@state.co.us.

Per the request of Wendy Anderson, the September CPS electronic newsletter, the E-Capsulette, included the notification by The Division of Registrations that it has outsourced the production of wall certificates for its licensees to Wall Certificate Service (WCS) a division of Professional Credential Services, Inc. (PCS), effective July 1, 2009. Licensees will be able to order and pay the \$25 fee online.

Fifteen hours of CE will offered at the 2010 CPS Winter CE Seminar, January 10-13, 2010 at the Westin Riverfront Resort located at the base of Beaver Creek Mountain in Avon. Details are available on the CPS website www.copharm.org.

Governor’s Expert Emergency Epidemic Response Committee (GEEERC) – Paul Limberis, RPh

The GEEERC met October 1, 2009. Jeannine Dickerhofe reported the following regarding the influenza epidemic.

- All the seasonal flu supply should have been shipped by the end of September. That is not happening, mainly because the manufacturers are focused on preparing the H1N1 vaccine which has delayed supplies of seasonal flu being sent on a timely basis.
- Providers were contacted to see if they could administer the H1N1 vaccine in their practices in Colorado. Over 1400 providers responded.
- The first shipment of the H1N1 vaccine arrived on September 30, 2009. This was the live attenuated vaccine (FluMist). Most of the future vaccine to be received will be the killed vaccine. Week 1 supply was 53,000 doses. Week 2 is expected to be around 70,000 doses and Week 3 should be a much larger quantity. Healthcare workers are targeted in the first wave, with most doses going to public health departments, major health systems, etc.
- It was stated that some pediatricians are recommending that children not get the vaccine because the benefit does not outweigh the risk. However, Ned Calonge, Chief Medical Officer for the Colorado Department of Public Health and Environment ("CDPHE"), said the message is very consistent. "The best protection against H1N1 is to get the vaccine, especially in younger age groups."
- Denver Health Medical Center gave statistics that they have usually about 30-40 visits per day for influenza like illness (ILI). They are seeing over 160 visits per day in the last 4-5 days. Children's Hospital reported that influenza like illness patients normally are about 1/3 of their patients, but are now about 90% of the volume. The majority of patients being seen do not qualify to get antivirals. It's hard for parents to understand.
- It's important for patients with H1N1 to stay at home until 24 hours after the fever breaks in order not to spread the disease.
- Colorado Department of Public Health and Environment (CDPHE) has developed a new handbook called "Home Care Guide...Providing Care At Home During Pandemic Flu." This is being distributed through Public Health Departments and Healthcare Systems. This handbook is on the CDPHE website, as well as fact sheets and videos on how to care for ill household members. <http://www.cdphe.state.co.us/epr/Public/H1N1/HomeHealthcare/HomeHealthcare.html>
- Flyers to encourage the public to call CO HELP at 1-877-462-2911 for questions about the flu are being distributed through Wal-Mart, Walgreens, Safeway, other pharmacies, schools and other venues.
- Kaiser Permanente data was presented, illustrating that the number of patients being seen for influenza-like illness (ILI) has drastically increased in the past 4 weeks (going from less than 1% to about 6% for the week ending on 9/26/09). Kaiser sees an average of 15,000 to 20,000 patients per week in Primary Care. The 2009-2010 flu season surveillance began with week ending September 5th.
- People are using the CDPHE website. Over 35,000 hits were made in September.

- Tamiflu liquid in the stockpile expires June 30, 2009, but that expiration date has been extended. The first supply of Tamiflu capsules in the stockpile expires December 31, 2009, but the rest has a much longer dating. Again, extended dating could be applied to this supply.
- There is a concern that we might not have enough vaccinators. There is consideration for using Executive Order 5.0, which allows the expansion of scope of practice to increase the number of vaccinators. Examples would be to use Emergency Medical Technicians (EMTs) and to allow physicians to supervise more than two Physician Assistants (PAs) at one time. It was also discussed that dentists, veterinarians and pharmacists could be added to the list of vaccinators with some "just in time" training.

Intern & School Relations – Jeannine Dickerhofe, RPh

Cathy Jarvis reported on the Accreditation Council for Pharmacy Education's recent site visit to the University of Colorado School of Pharmacy. She stated that a final report should be out in February 2010. In addition, she updated the Board on the progress of the School's new building.

Dr. Lane Brunner, PhD, provided the Board with an update on Regis University School of Pharmacy.

Legislation - Jeannine Dickerhofe, RPh.

The Colorado Pharmacists Society, RxPlus and the Colorado Retail Council have met with the Department of Health Care Policy and Financing and requested that the Department consider an adjustment of Average Wholesale Price ("AWP") to offset the losses that pharmacies will experience as a result of the First Data Bank ("FDB") lawsuit. The National Community Pharmacists Association, the National Alliance of State Pharmacy Association Executives, and the National Association of Chain Drug Stores sent a letter on September 8, 2009 to The Honorable Kathleen Sebelius, Secretary of the U.S. Department of Health and Human Services, detailing concerns about the impact of the First Databank settlement on Medicaid patients' access to pharmacy services and also requested an adjustment of AWP. A letter was sent by Carol H. Steckel of the National Association of State Medicaid Directors on September 18 to all Medicaid directors stating that pharmacies were "unjustly enriched" by an artificial increase in AWP, and that therefore, no action should be taken by Medicaid agencies in the states.

The Colorado Pharmacists Society, RxPlus and the Colorado Retail Council sent a letter to the Colorado Medicaid Director, Dr. Sandeep Wadhwa, stating that we believe that Colorado pharmacies were not "unjustly enriched" by the First Databank action. State action to reduce pharmacy payments directly offset the FDB increase in AWP. In June of 2001, the Colorado Medicaid rate for brand name drugs was reduced from AWP-10%+\$4.08 to AWP-11%+\$4.00. In July of 2002 the rate was again reduced to AWP-14%, and in October of 2002, was increased to AWP-13.5%. The most recent reductions now put the Medicaid rate of reimbursement at AWP-14.5%. The FDB lawsuit would reduce the rate of reimbursement by another 4%. This 4% reduction, based on 2008 Medicaid claims, equates to a \$7 million loss for pharmacies.

Rules – Rich Doyle

None

Inspectors

SeniorMed pharmacy, PDO 7-53

The Board considered a memorandum from Ms. Martin. After due consideration, the Board voted to initiate a complaint against the pharmacy.

Walgreen Pharmacy Computer System

The Board considered a memorandum from Mr. Gassen. Mr. Gassen will provide an update with additional information at an upcoming meeting after additional monitoring is conducted.

OLD BUSINESS

Stipulations

Leonard McGinnity, RPH 9625

The Board reviewed Mr. McGinnity's request for release from his stipulation and final agency order. After due consideration, the Board voted to refer the matter to Executive Session for legal guidance.

After Executive Session, the Board voted to deny the request and inform Mr. McGinnity that he must continue with his stipulation until he can show an additional consecutive six-months of satisfactory compliance with his stipulation and commit no additional violations.

Miscellaneous

Automated Cassettes & Returned to Stock Prescriptions

The Board considered an agenda memorandum from Mr. Gassen. After due consideration, the Board decided to take no action at this time.

David Yang, RPH 17421

Ms. Anderson informed the Board that Mr. Yang had withdrawn his request.

NEW BUSINESS

Complaints

Aapex Community Pharmacy, Inc., OSP 5820

2010-0115

The Board voted unanimously to refer the case to Executive Session for discussion of possible disciplinary action.

After Executive Session, the Board voted to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

The Board, however, did vote to begin an additional investigation on the dispensing practices of this pharmacy.

Coram Specialty Infusion Services, PDO 37-24

2009-2224

The Board voted unanimously to refer the case to Executive Session for discussion of possible disciplinary action.

After Executive Session, the Board voted to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Ornes, Beverly, RPH 12044 **2010-0262**

The Board voted unanimously to refer the case to Executive Session for discussion of possible disciplinary action.

After Executive Session, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act.

Kociela, Daniel, RPH 10775 **2010-0485**

The Board voted unanimously to refer the case to Executive Session for discussion of possible disciplinary action.

After Executive Session, a motion was made, seconded, and carried to dismiss the case as being without merit.

McGinnity, Leonard D., RPH 9625 **2010-0267**

The Board voted unanimously to refer the case to Executive Session for discussion of possible disciplinary action.

After Executive Session, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act.

Nephew, Gary R., RPH 18350 **2010-0795**

Mary Arceneaux recused.

The Board voted unanimously to refer the case to Executive Session for discussion of possible disciplinary action.

After Executive Session, a motion was made, seconded, and carried to dismiss the case as being without merit. The Board did direct, however, that a Letter of Guidance be sent to Mr. Nephew.

Ornes, David S., RPH 12550 **2010-0469**

Paul Limberis recused.

The Board voted unanimously to refer the case to Executive Session for discussion of possible disciplinary action.

After Executive Session, the Board voted to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Robbins, Todd B., RPH 15952 **2010-0510**

The Board voted unanimously to refer the case to Executive Session for discipline.

Walgreen Pharmacy #3586, PDO 24-79 **2010-0274**

The Board voted unanimously to refer the case to Executive Session for discipline.

Walgreen Pharmacy #12380, PDO 216 **2010-0688**

The Board voted unanimously to refer the case to Executive Session for discipline.

Walgreens Distribution Center, WHO 7161 **2010-0689**

The Board voted unanimously to refer the case to Executive Session for discipline.

Cardinal Health Pharmaceutical Supply, WHI 6012 **2010-0690**

The Board voted unanimously to refer the case to Executive Session for discipline.

Wal-Mart Pharmacy #10-3805, PDO 703 **2010-0461**

The Board voted unanimously to refer the case to Executive Session for discussion of possible disciplinary action.

After Executive Session, the Board voted to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Wolfe, Jamie L., RPH 14044 **2010-0110**

The Board voted unanimously to refer the case to Executive Session for discipline.

LICENSING

Other Outlets, New

The Board approved the registration of 0 new other outlets

Prescription Drug Outlets, New (In-State)

The Board approved the registrations of 8 new in-state prescription drug outlets.

Prescription Drug Outlets, New (Out-of-State)

The Board approved the registrations of 2 new nonresident prescription drug outlets.

Manufacturers, New

The Board approved the registrations of no new manufacturers.

Limited Licenses, New

The Board approved the registrations of no new limited licenses.

Wholesalers, New (In-State)

The Board approved the registrations of 2 new in-state Wholesalers.

Wholesalers, New (Out-of-State)

The Board approved the registrations of 6 new out-of-state Wholesalers.

Licensure by Examination and Score Transfer

The Board ratified the licensure of 34 applicants for licensure.

Licensure by License Transfer

The Board ratified the licensure of 12 applicants seeking licensure through license transfer. It was noted that these licensees met all of the requirements for licensing under the provisions of section 12-22-116, C.R.S.

LICENSURE ISSUES

McKesson Corporation, Out-of-State Wholesaler Applicant, Case 2009-2366

After review of the available information, the Board voted to rescind the referral of the case to the Office of the Attorney General, and allowed the applicant to withdraw its application.

Orlando R. Garcia, Pharmacy Intern Applicant

After review of the available information, the Board voted to refer the matter to Executive Session for discussion of license sanctions.

After Executive Session, the Board voted to deny the application and refer the matter for discipline.

Colorado Human Society, Limited License Reinstatement Applicant

After review of the available information, the Board voted to refer the matter to Executive Session for discussion with Legal Counsel.

After Executive Session, the Board voted to approve the application.

MISCELLANEOUS

Correspondence, etc.

Correspondence from a Walgreen's Pharmacist

The Board decided that no further action was necessary.

Kaiser Permanente Request for Modification to Rule 6.00.00

Jeannine Dickerhofe recused.

After due consideration, the Board voted to table the request and refer the matter to the Board of Medical Examiners for comment.

NABP Recommendations on Prescription Labels

The Board noted the information, deciding that no further action was needed.

EXECUTIVE SESSION

At 11:27 am, Board President Paul Limberis moved that that the Board enter into Executive Session to discuss with counsel disputes that are the subject of pending or imminent litigation, specific claims or grievances, or legal advice on specific legal questions, pursuant to CRS section 24-6-402 subsection (3)(a) roman (II), and matters required to be kept confidential by federal law or rules or state statutes pursuant to CRS sections 24-6-402 subsection (3)(a) roman (III) and 12-22-125.2 subsection (7)(a) including:

- Discussion with counsel regarding the Case Status Report for matters that have been referred to the Expedited Settlement Program, including settlement negotiations, counteroffers and other legal questions;
- Discussion with counsel regarding the legal basis for potential application denial, confidential letters of concern, disciplinary action, and, where warranted recommended settlement guidance regarding on all matters referred to Executive Session earlier in the meeting;
- Discussion with counsel regarding legal questions pertaining to the Case Status Report of the Office of the Attorney General and a counteroffer on case 2009-4076.

Mr. Limberis further moved that the Board enter into Executive Session for the purpose of discussing reports of malpractice claim settlements required to be kept confidential by federal law or rules or state statutes pursuant to CRS 24-6-402 subsection (3)(a) roman (III), and CRS section 12-22-113.5 subsection 3, including case numbers: 2010-0734 and 2010-0593.

In addition, the Board President moved that the Board enter into Executive session for the purpose of discussing matters required to be kept confidential by federal law or rules or state statutes pursuant to CRS section 24-6-402 subsection (3)(a) roman (III) to include the Peer Assistance Services reports of Kevin Potts, RPH, and Jason McCanless, RPH.

Patient medical records are confidential pursuant to CRS section 25-1-1201 et seq. and CRS 13-90-107 subsection (1)(d). Drug and alcohol treatment records are also confidential pursuant to 42 Code of Federal Regulations Part 2, Article 21, Part 12, and CRS section 13-90-107.

The motion was seconded. The vote was unanimous with six votes approving the motion to go into Executive Session and none opposing.

The Board exited Executive Session at 2:41 pm.

Open Session

Kevin Potts, RPH

The Board found that it has reasonable grounds to believe that the public health, safety, or welfare imperatively required emergency action and voted to summarily suspend Mr. Potts' license if he didn't enter into an agreement to cease practice by November 2, 2009.

Case 2010-0734

The Board voted to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Case 2010-0593

The Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act.

GlobalNet Pharmacies, OSP 5648, Case 2009-1930

The Board voted to rescind the referral of this case to the Office of the Attorney General, and voted to dismiss the case.

ADJOURNMENT

The Board adjourned at approximately 2:51 p.m.

Approved by Paul Limberis, R.Ph., President Date: November 19, 2009